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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/828,615 | 04/06/2001 | William C. Olson | 64672/JPW/SHS/NS | 5850 |

7590

06/25/2002

Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

STUCKER, JEFFREY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

DATE MAILED: 06/25/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Other Notice to Comply

Office Action Summary

Serial Number: 09/828615
Art Unit: 1648

2

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **Failure to comply with these requirements in response to this Office Action will be considered to be non-response and may result in abandonment of this application.**

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio
(<http://www.uspto.gov/ebs/efs/downloads/documents.htm>), EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other delivery service to:
U. S. Patent and Trademark Office
2011 South Clark Place

Serial Number: 09/828615
Art Unit: 1648

3

**Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202**

**4. Hand Carried directly to the Customer Window at:
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202**

The following is a quotation of the second paragraph of
35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-10 are vague and indefinite. Does the method require that the viral load be reduced prior to treatment with the antibodies or is the reduction relative to the viral load prior to treatment? It is recommended that the claims be amended to insert after "wherein" the phrase "after treatment".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 21, and 22 are rejected under 35 U.S.C. § 102(a) as being anticipated by Olson et al. (WO 0035409).

Olson et al. teach inhibiting the fusion of HIV-1 with CD4+ CCR5+ cells by treating the cells with anti-CCR5 antibodies. The reference specifically recites the same monoclonal antibodies as is claimed in the instant invention, namely, PA8, PA9, PA10, PA11, PA12, and PA14. The amount of viral load reduction would be expected to be the same because it is a property of the of the specific antibodies that are administered. Olson et al. teach on pages 13 and 20 that the antibody can be humanized. It is disclosed on page 19 that the antibodies can be administered by intravenous, intramuscular, or subcutaneous means. Therefore, the instant invention is anticipated by Olson et al.

Claims 1, 2, and 5-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vila-Coro et al. (PNAS 3/00).

Vila-Coro et al. teach that the administration of the disclosed antibody reduces HIV-1 (represented by RNA copy number)

10 fold for at least two weeks compared to animals treated with a control antibody. Therefore, the instant invention is anticipated by Vila-Coro et al.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-22 are rejected under 35 U.S.C. § 103(a) as obvious over Olson et al. (WO 0035409).

The relevance of the reference has been given above. It does not specifically teach the claimed dosages or schedule of administration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the treatment

regime to optimizes the individual patient's response to the treatment. The claimed dosages fall within the disclosed range of dosages on page 19 as well as the time intervals of multiple doses which "can be determined without undue experimentation by one skilled in the art." Therefore, the instant invention is obvious over Olson et al. (WO 0035409).

Claims 1-22 are rejected under 35 U.S.C. § 103(a) as obvious over Vila-Coro et al. (PNAS, 3/00).

The relevance of the reference has been given above. It does not specifically teach the claimed dosages or schedule of administration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the treatment regime to optimizes the individual patient's response to the treatment. The claimed dosages as well as the time intervals of multiple doses can be determined without undue experimentation by one skilled in the art. Therefore, the instant invention is obvious over Vila-Coro et al.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Serial Number: 09/828615
Art Unit: 1648

7

Olson et al. (J. of Virol., 1999) discloses the instantly claimed monoclonal antibodies but there is no reasonable expectation of success in using these antibodies to treat HIV infection.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

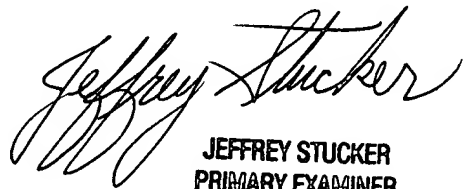
The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JEFFREY STUCKER
PRIMARY EXAMINER

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ 7.

Other: _____

Applicant must provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
 For CRF submission help, call (703) 308-4212
 For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.